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July 14, 2022

## **Re: Comments on FEIS's Lack of a Serious Analysis of Impacts to Public Health**

Dear Josh Tulkin and the Sierra Club Maryland Chapter:

I have reviewed the I-495 and I-270 Managed Lanes Study Final Environmental Impact Statement (FEIS) Chapters 1–3, Chapter 5 sections 1–3, 5–11, and 21–23, Chapters 7–9, Appendix (App'x) F sections 1–5, App'x K sections 1–4, App'x L Executive Summary, App'x Q sections 1–3 and Appendix A, and App'x T.6 in order to assess whether the FEIS adequately evaluated the public health impacts of the proposed MLS, from my perspective as an epidemiologist since 1980 with experience that includes environmental epidemiology training, observational (“real world”) epidemiology research and methods development, and federal review of medical epidemiology studies and other documents. See attached CV. In my professional opinion, the FEIS fails to adequately address and review the adverse health effects of the Preferred Alternative.

The Preferred Alternative, known as Phase 1 South, will increase traffic on the highways by creating induced demand. The FEIS states that transportation improvements will result in economic growth and population growth, which it acknowledges will increase traffic and demand for further transportation improvements. See FEIS § 9.3.4.N. Yet, the FEIS ignores the indirect and cumulative effects of the increased traffic and construction for the Preferred Alternative, including, importantly, by failing to discuss and quantify its health impacts. This failure violates NEPA’s mandate to “assure for all Americans safe, healthful, productive, and aesthetically and culturally pleasing surroundings,” 42 U.S.C. § 4331, and to “attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences.” Id. § 4331. NEPA’s mandate requires agencies to incorporate impacts on the human health into any comprehensive EIS. The Agencies fail to do so here.

Before discussing specific health impacts, it must be noted that the Agencies appear to be manipulating their traffic models to reduce the area with anticipated indirect and cumulative effects. While the area of traffic influence was initially modeled to include upper Montgomery and Frederick Counties, the Agencies reduced the modeled area of influence:

[s]similar to the DEIS, the MWCOG model initially resulted in a relatively large, affected network area. In consultation with FHWA, additional steps were taken to reduce the footprint of the affected network area to make it more consistent with the Preferred Alternative study area. These included eliminating the travel time criterion and removing modeling artifacts.

FEIS App'x K § 3.3.2.B. Thus, for all discussed impacts, the Agencies seem to have artificially constrained the model to avoid evaluating the full impacts of the Preferred Alternative, health-related or otherwise. For example, the FEIS largely ignores the network impacts of the Preferred Alternative by declining to address impacts to feeder roads, local and other smaller regional roads,

and alternative routes affected by the Preferred Alternative.<sup>1</sup> Moreover, each health impact discussed below that the Agencies ignored is compounded by the Agencies' failure to consider the entire geographic area affected by the Preferred Alternative, including those smaller and regional roads.

First, the FEIS ignores the obvious increase in traffic-related injuries and death from the increase in vehicle miles traveled in private vehicles predicted under the Preferred Alternative. It also does not discuss the likely increase in road deaths from pedestrians and cyclists,<sup>2</sup> risks that are higher in the United States than in 28 other high-income countries.<sup>3</sup>

Second, the FEIS does not quantify impacts to health from mobile source air toxic (MSAT) emissions or other health impacts from traffic-caused air pollution. The FEIS says:

Per FHWA's Updated Interim Guidance on MSAT Analysis in NEPA Documents (2018), information is incomplete or unavailable to credibly predict the project-specific health impacts due to changes in MSAT emissions associated with a proposed set of highway alternatives. The outcome of such an assessment, adverse or not, would be influenced more by the uncertainty introduced into the process through assumption and speculation rather than any genuine insight into the actual health impacts directly attributable to MSAT exposure associated with a proposed action.

These limitations impede the ability to evaluate how potential public health risks posed by MSAT exposure should be factored into project-level decision-making within the context of a NEPA Study such as the Study. However, the Final Air Quality Technical Report for the FEIS includes a more detailed discussion of the uncertainties associated with predicting health impacts of project alternatives. Refer to FEIS, Appendix K. The FEIS summarizes that "[a]ir toxics emissions from mobile sources have the potential to impact human health" (FHWA, 2018).

FEIS at § 9.3.4.L (9-56). The Agencies decline to quantify MSAT impacts by relying on an FHWA-funded, 2010 Health Effects Institute literature review which concludes that there is a

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<sup>1</sup> While the FEIS claims that vehicle miles traveled on local roads will decrease under the Preferred Alternative, FEIS § 5.8.3.B, this claim makes no sense because more vehicles on the highway will lead to more vehicle miles on local roads.

<sup>2</sup> Morency P, et al. Traveling by Bus Instead of Car on Urban Major Roads: Safety Benefits for Vehicle Occupants, Pedestrians, and Cyclists. *J Urban Health*. 2018 Apr; 95(2): 196–207. DOI: 10.1007/s11524-017-0222-6; Beck LF, Dellinger AM, O'Neil ME. 2007. Motor Vehicle Crash Injury Rates by Mode of Travel, United States: Using Exposure-Based Methods to Quantify Differences. *American Journal of Epidemiology* 166(2): 212-218. doi: 10.1093/aje/kwm064; Savage I. Comparing the Fatality Risks in United States Transportation Across Modes and Over Time. *Research in Transportation Economics*. 2013; 43(1):9-22. DOI: 10.1016/j.retrec.2012.12.011. <https://faculty.wcas.northwestern.edu/ipsavage/436.pdf>.

<sup>3</sup> Yellman MA, Sauber-Schatz EK. Motor Vehicle Crash Deaths — United States and 28 Other High-Income Countries, 2015 and 2019. *Morbidity and Mortality Weekly Report*. July 1, 2022. 71(26):837-843.

[https://www.cdc.gov/mmwr/volumes/71/wr/mm7126a1.htm?s\\_cid=mm7126a1\\_w](https://www.cdc.gov/mmwr/volumes/71/wr/mm7126a1.htm?s_cid=mm7126a1_w).

“causal relationship between exposure to traffic-related air pollution and exacerbation of asthma” and a suggestive causal relationship for other health impacts from air pollution, but ultimately concludes that for several health outcomes, the data were inadequate or insufficient to draw firmer conclusions. FEIS § 9.3.4.L. However, much more research has been done since 2010, and the FEIS should have considered and reviewed that literature. Recent research finds a causal relation between even low-levels of traffic-caused air pollution and ill health in children and adults, including lung problems (asthma, pneumonia), cardiovascular problems (myocardial infarction), poor pregnancy outcomes, poor physical growth, school absences, reduced cognitive abilities (autism, academic performance, dementia), and earlier mortality.<sup>4</sup>

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<sup>4</sup> Ernani F. Choma, et al., Health Benefits of Decreases in On-Road Transportation Emissions in the United States from 2008 to 2017, PNAS 118(51) (Dec. 2021), *available at* doi: 10.1073/pnas.2107402118; Luo Z et al. Impacts of Vehicle Emission on Air Quality and Human Health in China, Science of the Total Environment, Vol. 813 (Mar. 20, 2022), *available at* <https://doi.org/10.1016/j.scitotenv.2021.152655>; WHO-Europe, Health Effects of Transport-Related Air Pollution, *available at* [https://www.euro.who.int/\\_data/assets/pdf\\_file/0006/74715/E86650.pdf](https://www.euro.who.int/_data/assets/pdf_file/0006/74715/E86650.pdf); Kheirbek I, et al., The Contribution of Motor Vehicle Emissions to Ambient Fine Particulate Matter Public Health Impacts in New York City: A Health Burden Assessment, Environmental Health (2016) 15:89, *available at* DOI 10.1186/s12940-016-0172-6; McCubbin DR, et al., The Health Costs of Motor-Vehicle-Related Air Pollution, Journal of Transport Economics and Policy, Vol. 33(3):253-86 (Sep. 1999), *available at* <https://www.jstor.org/stable/20053815>; Anderson, Michael L, As the Wind Blows: The Effects of Long-Term Exposure to Air Pollution on Mortality, Journal of the European Economic Association 18(4): 1886-1927 (Aug. 2020), *available at* DOI: 10.1093/jeea/jvz051; Austin, Wes, et al., School Bus Emissions, Student Health and Academic Performance, Economics of Education Review (2019) *available at* <https://www.nber.org/papers/w25641>, DOI: 10.3386/w25641; Beatty, Timothy KM and Jay P Shimshack, School Buses, Diesel Emissions, and Respiratory Health, Journal of Health Economics, 30(5): 987–999 (2011), *available at* DOI: 10.1016/j.jhealeco.2011.05.017; Bell, Michelle L, et al., Ozone and Short-Term Mortality in 95 U.S. Urban Communities, 1987-2000, Journal of the American Medical Association, 292(19), 2372–2378 (2004), *available at* DOI: 10.1001/jama.292.19.2372; Bell, Michelle L. et al, Challenges and Recommendations for the Study of Socioeconomic Factors and Air Pollution Health Effects, Environmental Science and Policy 8 (5): 525–533 (2005), *available at* <https://doi.org/10.1016/j.envsci.2005.06.003>; Benmarhnia, Tarik, et al., Using Instrumental Variables Under Partial Observability of Endogenous Variables for Assessing Effects of Air Pollution on Health (2017), *available at* <https://mauricio-romero.com/pdfs/papers/partialiv.pdf>; Bishop, Kelly C., et al., Hazed and Confused: The Effect of Air Pollution on Dementia, Technical Report, NBER Working Paper No. 24970 (2018), *available at* <https://www.nber.org/papers/w24970>; Case, Anne, et al, The Lasting Impact of Childhood Health and Circumstance, Journal of Health Economics 24(2): 365–389 (2005), *available at* DOI: 10.1016/j.jhealeco.2004.09.008; Currie, Janet, et al., Air Pollution and Infant Health: What Can We Learn from California’s Recent Experience?, The Quarterly Journal of Economics 120(3): 1003–1030 (2005), *available at* <https://www.jstor.org/stable/25098761>; Currie, Janet et al., Traffic Congestion and Infant Health: Evidence From E-ZPass, American Economic Journal: Applied Economics 3(1):65–90 (2011),

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available at <https://www.aeaweb.org/articles?id=10.1257/app.3.1.65>; Currie, Janet et al, Does Pollution Increase School Absences?, *Review of Economics and Statistics* 91(4): 672–694 (2009); Currie, Janet et al, What Do We Know About Short-and Long-Term Effects of Early-Life Exposure To Pollution?, *Annu. Rev. Resour. Econ.* 6(1): 217–247 (, 2014), available at <http://www.nber.org/papers/w19571.pdf>; Currie, Janet et al., Air Pollution and Infant Health: Lessons From New Jersey, *Journal of Health Economics*, 28(3): 688–703 (2009), available at DOI: 10.1016/j.jhealeco.2009.02.001; Di, Qian, et al., Association of Short-Term Exposure to Air Pollution With Mortality in Older Adults, *Journal of the American Medical Association*, 318(24): 2446–2456 (2017); Dominici, Francesca, et al., Science and Regulation. Particulate Matter Matters, *Science*, 344(6181): 257–259 (2014), available at DOI: 10.1126/science.1247348; Gauderman, W. et al., Childhood Asthma and Exposure To Traffic and Nitrogen Dioxide, *Epidemiology*, 16(6): 737–743 (2005), available at DOI: 10.1097/01.ede.0000181308.51440.75; Gauderman WJ, et al. Effect of Exposure to Traffic on Lung Development From 10 to 18 Years of Age: A Cohort Study, *Lancet* 369(9561):571-7 (Feb. 17, 2007). available at DOI: 10.1016/S0140-6736(07)60037-3; Gent, Janneane F., et al., Association of Low-Level Ozone and Fine Particles with Respiratory Symptoms in Children with Asthma, *Journal of the American Medical Association*, 290(14): 1859–1867 (2003), available at DOI: 10.1001/jama.290.14.1859; Hoek, Gerard, et al., Long-Term Air Pollution Exposure and Cardio-Respiratory Mortality: A Review, *Environmental Health*, 12(43) (2013), available at DOI: 10.1186/1476-069X-12-43; Hyder, Ayaz, et al., PM2.5 Exposure and Birth Outcomes: Use of Satellite- and Monitor-Based Data, *Epidemiology* 25(1): 58 (2014), available at DOI: 10.1097/EDE.0000000000000027; Isen, Adam, et al., Every Breath You Take—Every Dollar You’ll Make: The Long-Term Consequences of the Clean Air Act of 1970, *Journal of Political Economy* 125(3): 848–902 (2017), available at <https://www.journals.uchicago.edu/doi/abs/10.1086/691465>; Jerrett, Michael, et al., Long-Term Ozone Exposure and Mortality, *New England Journal of Medicine* 360(11): 1085–1095 (2009), available at DOI: 10.1056/NEJMoa0803894; Jerrett M, et al., Traffic-Related Air Pollution and Asthma Onset in Children: A Prospective Cohort Study With Individual Exposure Measurement, *Environ Health Prospect* 116(10):1433-8 (Oct. 2008), available at DOI: 10.1289/ehp.10968; Knittel, Christopher R, et al., Caution, Drivers! Children Present: Traffic, Pollution, and Infant Health, *Review of Economics and Statistics* 98(2): 350–366 2016. <http://hdl.handle.net/1721.1/113913>; Krewski D, et al., Extended Follow-up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality, *Res Rep Health Eff Inst.* (140): 5-114, 115-36 (May 2009); Lleras-Muney, Adriana, The Needs of the Army Using Compulsory Relocation in the Military to Estimate the Effect of Air Pollutants on Children’s Health, *Journal of Human Resources*, 45(3): 549–590 (2010), available at <https://www.jstor.org/stable/25703469>; Mar, Therese F. and Jane Q. Koenig, Relationship Between Visits to Emergency Departments for Asthma and Ozone Exposure in Greater Seattle, Washington, *Annals of Allergy, Asthma, and Immunology* 103(6): 474–479 (2009), available at DOI: 10.1016/S1081-1206(10)60263-3; Marcus, Michelle, On the Road to Recovery: Gasoline Content Regulations and Child Health, *Journal of Health Economics*, 54: 98–123 (2017), available at DOI: 10.1016/j.jhealeco.2017.04.003; McConnell R, et al. Traffic, Susceptibility, and Childhood Asthma, *Environ Health Prospect* 114(5):766-72 (May 2006), available at DOI: 10.1289/ehp.8594; McConnell R, et al. Childhood Incident Asthma and Traffic-Related Air Pollution at Home and School, *Environ. Health Perspect.* 118(7): 1021-6 (July 2010), available

Third, the FEIS also understates the impacts of the Preferred Alternative on MSAT emissions. While the FEIS explains numerous times that, under the Preferred Alternative, MSAT emissions are expected to “significantly decline in the Opening (2025) and Design (2040) years when compared to base conditions (2016),” see, e.g., FEIS § 9.3.4.F, the FEIS tables showing the MSAT data reveal that projected MSATs are *lower* under the No Build alternative. FEIS App’x. K, Tbl. 3-1. The FEIS of course does not grapple with this discrepancy. Recent research has shown that some air quality monitoring is manipulated to undermeasure poor air quality.<sup>5</sup> It is possible

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<sup>5</sup> Grainger, Corbett, et al., Do Regulators Strategically Avoid Pollution Hotspots When Siting Monitors? Evidence from Remote Sensing of Air Pollution, 2016; Grainger, Corbet, and Andrew Schreiber. Discrimination in Ambient Air Pollution Monitoring? AEA Papers and Proceedings. 109: 277-82 (May 2019), *available at* <https://www.aeaweb.org/articles?id=10.1257/pandp.20191063>; Mu Y, Rubin E, Zou E. What’s Missing in Environmental (Self-)monitoring: Evidence from Strategic Shutdowns of Pollution Monitors. NBER Working Paper No. w28735. Last revised 15 May 2022, *available at* <http://www.nber.org/papers/w28735>; Zou, Eric. Unwatched Pollution: the Effect of Intermittent

that the data used in the FEIS monitors may not be accurate so that the baseline data used in the FEIS are also inaccurate.

Fourth, the FEIS fails to adequately discuss mobile source pollution from tire and brake wear.<sup>6</sup> As noted in a recent article:<sup>7</sup>

Every time a car brakes, accelerates, or changes direction, the friction wears down the exterior of the tire, sending particles into the environment. Some remain suspended in the air, and others get swept into local waterways, where they can have devastating effects on plant and animal life. ... The vulcanized rubber compound that makes up the outermost layer, the tread, often contains sulfur, zinc, carbon black, bisphenol A (BPA), and other chemicals. A lot of that gets swept off the roads by rain, along with motor oil, bits of pavement, and other litter.

When particulate matter (PM<sub>2.5</sub> and PM<sub>10</sub>) air quality analyses are done, tire and brake wear are typically components of the analysis. Non-exhaust emissions—particles released into the air from brake wear, tire wear, road surface wear and resuspension of road dust during on-road vehicle usage—are currently believed to constitute the majority of primary particulate matter from road transport, 60 percent of PM<sub>2.5</sub> and 73 percent of PM<sub>10</sub>.<sup>8</sup>

Fifth, the FEIS fails to discuss the health hazards caused during the construction process because of increased silica dust in construction areas. The impacts of increased silica dust were described in comments submitted by Byron Bloch, an auto safety expert, SDEIS, App. T.6.B.2 at C-95-C-107, but the FEIS fails to respond adequately to these important comments.

Sixth, while the FEIS acknowledges the need for barriers to reduce noise impacts, the FEIS generally fails to acknowledge the long-term health impacts of noise “leakage” at the highway entrance or exits or on other roads affected by the Preferred Alternative. The health impacts of traffic noise, including heart disease, blood pressure, brain damage, and cancer, are well recognized.<sup>9</sup> The FEIS focuses only on the health impacts from noise during construction and does

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Monitoring on Air Quality, *American Economic Review*. 111(7): 2101-26 (Oct. 2017), *available at* <https://files.webservices.illinois.edu/7199/zoueric-jmp.pdf>.

<sup>6</sup> Beate Baensch-Baltruschat, et al., Tyre and Road Wear Particles (TRWP) - A Review of Generation, Properties, Emissions, Human Health Risk, Ecotoxicity, and Fate in the Environment, *Science of The Total Environment* 733 (2020).

<sup>7</sup> Lindsey McGinnis, A pollution solution where the rubber meets the road, *The Christian Science Monitor* (Nov. 9, 2020), *available at* <https://www.csmonitor.com/Environment/2020/1109/A-pollution-solution-where-the-rubber-meets-the-road>.

<sup>8</sup> Press Release: Pollution From Tyre Wear 1,000 Times Worse Than Exhaust Emissions, *Emissions Analytics* (Mar. 6, 2020), *available at* <https://www.emissionsanalytics.com/news/pollution-tyre-wear-worse-exhaust-emissions>.

<sup>9</sup> Babisch W, et al., Blood Pressure of 8-14 year old Children in Relation to Traffic Noise at Home--Results of the German Environmental Survey for Children (GerES IV), *Sci Total Environ*. 407(22):5839-43 (Nov. 1, 2009), *available at* DOI: 10.1016/j.scitotenv.2009.08.016;

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not fully address the health impacts from the anticipated long-term increases in noise under the Preferred Alternative or meaningfully consider the literature describing adverse health impacts from noise.

Seventh, the FEIS acknowledges that the Preferred Alternative will remove many acres of green space and trees along the route, see e.g., FEIS at 5-97, 5-107-5-108, 5-180, but fails to discuss the adverse impacts of a decrease in green space like health-related decreases in quality of life.<sup>10</sup>

Eighth, as discussed in Dr. Bialek's comments on the FEIS, the soil near the roadways contains lead deposited during the decades when motor vehicles used leaded gasoline. The DEIS explains that the companies implementing the Preferred Alternative must test the soil and mitigate lead hazards. See DEIS at R-30. However, the FEIS does not discuss any soil sampling or the extent of proposed testing and mitigation, how much that mitigation might cost, or how it will be performed, nor when or how the health impacts from activities disturbing lead-contaminated soil will be mitigated. There is no indication that that any final approval of the Preferred Alternative

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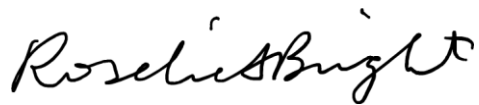
<sup>10</sup> Alizadeh G, et al., Social, Economic, Technological, and Environmental Factors Affecting Cardiovascular Diseases: A Systematic Review and Thematic Analysis, *Int J Prev Med.* 13:78 (April 2022), *available at* <https://www.ijpvmjournal.net/article.asp?issn=2008-7802;year=2022;volume=13;issue=1;spage=78;epage=78;aulast=Alizadeh?type=0>; Moitra S, et al., Roles of the Physical Environment in Health-Related Quality of Life in Patients with Chronic Obstructive Pulmonary Disease, *Environ Res.* 203:111828 (Jan. 2022), *available at* DOI: 10.1016/j.envres.2021.111828; Bereziartua A, et al., Exposure to Surrounding Greenness and Natural-Cause and Cause-Specific Mortality in the ELAPSE Pooled Cohort, *Environ Int.* 11:166:107341 (June 2022), *available at* DOI: 10.1016/j.envint.2022.107341.

will be conditioned on a binding obligation on the part of the companies to mitigate this serious impact.

Ninth, the FEIS does not address impacts from platinum and other palladium group substances that are emitted by catalytic converters as air emissions and contaminate soil and water through air deposition. In fact, the FEIS does not even mention the health impacts from these toxic substances, even though recent studies have characterized these impacts.<sup>11</sup>

Thank you for allowing me to submit this letter as part of your Chapter's review of the FEIS document.

Sincerely,

A handwritten signature in black ink that reads "Roselie Ann Bright". The signature is written in a cursive, flowing style.

Roselie Ann Bright, Sc.D., M.S.

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<sup>11</sup> Khaiwal Ravindra, et al., Platinum Group Elements in the Environment and Their Health Risk, *Sci Total Environ* 318(1-3):1-43 (Jan. 5, 2004), DOI: 10.1016/S0048-9697(03)00372-3; Wiseman, CLS et al., Platinum Group Element and Cerium Concentrations in Roadside Environments in Toronto, Canada, *Chemosphere*, 145:61-7 (Feb. 2016), DOI: 10.1016/j.chemosphere.2015.11.056; Savignan L, et al., Platinum Group Elements Contamination in Soils: Review of the Current State, *Chemosphere* 271:129517 (2021 May), DOI: 10.1016/j.chemosphere.2020.129517.

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## PERMANENT POSITIONS

8/2015-12/2021 **Epidemiologist 15** (as of 9/30/2018), **Epidemiologist 14** (10/2017 – 9/2018) and **Project Manager 14** (8/2015 – 10/2017), Office of Health Informatics, Office of the Chief Scientist (OCS), Office of the Commissioner (OC), then realigned 9/2021 to Office of Data Analytics & Research, Office of Digital Transformation, OC, Food and Drug Administration (FDA), Silver Spring, MD.

Led “Shakespeare”, a project that investigated my original idea: whether modern big data-type (meaning-free) text mining methods might be useful for real time surveillance of the notes in electronic health records to detect deaths and serious adverse events related to FDA-regulated products. We published our demonstration that our new, original method finds potential adverse events in clinical notes even if the writer did not attribute the event to a possible cause. If adopted, this technique could fill the gaps left by other projects that are using machine learning and natural language processing to derive standard codes from text notes: only known entities can be coded, and the coding rules are taking many years to develop. The project won training and coaching for innovations in the HHS IDEA Lab Ignite competitive cycle of 2015/2016. The tool could be used to monitor the impacts of FDA-regulated products on people’s health, monitor the consequences of medical countermeasure administration during emergencies, and also detect events of interest to other agencies and entities (CDC [infections], EPA [environmental hazards], FBI [criminal activity], AHRQ [patient safety threats], state and local agencies, and private healthcare businesses.

Represented FDA on the cross-federal Health IT Research & Development group (HITRD). I made major contributions to the HITRD Strategic Framework that was published on 5/30/2017 in the Federal Register and on the Networking and Information Technology Research and Development site in 2020.

4/2014-8/2015 **Project Manager 14**, Office of Informatics and Technology Innovation (OITI), Office of Information Management and Technology, Office of Operations (OO), OC, FDA, Silver Spring, MD.

Supported the health IT and IT governance aspects of the responsibilities of the FDA Chief Health Informatics Officer, who was also the Director of OITI.

1/2013-4/2014 **Project Manager 14**, Program Management Office (PMO), OITI, OC then OIM, OO), FDA, Silver Spring, MD.

12/2011-1/2013 **Project Manager 14**, Informatics Governance Staff, Office of the Chief Scientist, then realigned to Office of Operations, FDA, Silver Spring, MD.

9/2010 – 12/2011 **Program Manager 14**, realigned to Office of the Chief Scientist, OC, FDA, Rockville, MD.

4/2008 – 9/2010 **Program Manager 14**, Bioinformatics Board Staff, Office of Administration, OC, then Office of Operations, then Office of Scientific and Medical Programs, Office of the Commissioner, FDA, Rockville, MD. Temporary promotion to grade 15 (3/2009 – 7/2009).

10/2006 – 4/2008 **Supervisory Interdisciplinary Scientist 14, Chief**, Surveillance and Data Analysis Branch, Division of Compliance Risk Management and Surveillance, Office of Compliance, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), Rockville, MD.

7/1990 – 10/2006 **Mathematical Statistician 14** (11/1995 – 10/2006), **Mathematical Statistician 13** (11/1991 - 11/1995), and **Health Statistician 13** (7/1990 - 11/1991), Epidemiology Branch, Center for Devices and Radiological Health (CDRH), FDA, Rockville, MD. Division of Postmarket Surveillance (8/1994 -) or Division of Biometric Sciences (7/1990 - 8/1994), Office of Surveillance and Biometrics (7/1993 -) or Office of Science and Technology (7/1990 - 7/1993).

Promoted from grade 13 to 14 in 1996 as the official FDA expert in “case control” methodology for epidemiologic studies of non-radiological medical devices. Provided epidemiologic expertise to regulatory questions and conducted research on medical devices.

6/1984 - 6/1990 **Instructor** (3/1986 - 6/1990) and **Research Associate** (6/1984 - 2/1986), Department of Social Medicine, Harvard Medical School, and **Research Associate** (7/1989 - 6/1990), Department of Gerontology, Beth Israel Hospital, Boston, MA. . Supervisor was Jerry Avorn, MD, Harvard Medical School, Boston, MA, 02115, 617-732-1005. Worked full time 11/1985-6/1989 and half-time 6/1984-10/1985 and 7/1989-6/1990.

Epidemiologist in a team with physicians and programmers to develop raw Medicaid claims data into an epidemiologic database. Provided epidemiologic expertise and translated decisions made by investigative group into terms that the programmers could understand and implement. Wrote methods sections of two successful major funding proposals. Supervised a programmer and epidemiology assistant.

## **AFFILIATIONS**

- 2016 - 2021 FDA representative, Health Information Technology Research and Development Interagency Working Group, cross-Federal and coordinated by National Science Foundation. It is part of the Networking and Information Technology Research and Development Subcommittee of the National Science and Technology Council, led by the Director of the White House Office of Science and Technology Policy.
- 2014 - 2021 Editorial Consultant, many medical and epidemiology journals
- 2016 – 2019 Consultant, DHHS Innovation Lab, Washington, DC
- 2012 - 2013 Quality and Safety of Healthcare - Adverse Event Reporting Workgroup, HHS
- 2004 Methods Advisory Panel for the Institute of Medicine Committee on Postmarket Surveillance of Pediatric Medical Devices, National Academy of Sciences, Washington, DC
- 2003 - 2004 FDA representative, National Health Surveillance Network, DHHS
- 2003 Expert Panel Meeting on Health Information Technology, Agency for Healthcare Research and Quality (AHRQ)
- 2000 – 2002 Guest Editor, Proceedings of the Conference on Epidemiology of Medical Devices in Women, *Epidemiology* Supplement
- 2000 - 2002 FDA group advising the liaison to the Center for Education and Research Therapeutics Program administered by AHRQ
- 1998 Reviewer, *Epidemiology of Medical Devices*, an online “supercourse”
- 1992 Epidemiologist in ad hoc support of the Working Party on Exposure Guidelines for Chemical Mixtures, Federal Coordinating Committee for Science, Engineering, and Technology, U.S. Government
- 1990 - 1992 Rural Health Data Task Force, Public Health Service

## **HONORS, EXTERNAL TO FDA**

2008 Commended Award for the book, *Medical Device Epidemiology and Surveillance*, British Medical Association, United Kingdom

2003 Department of Health and Human Services (DHHS) Secretary's Award for Distinguished Service for leadership, teamwork and dedication in coordinating the integration of existing HHS Programs and systems to collect data on patient safety

2001 DHHS Secretary's Award for Distinguished Service as a member of the DHHS QuIC Patient Safety Report Team, for outstanding dedication, diplomacy, and diligence in developing the "QuIC Errors Report: Doing What Counts for Patient Safety"

## **DEGREES**

1/1979-3/1986 Doctor of Science (Epidemiology), **Harvard School of Public Health** (currently Harvard TH Chan School of Public Health), Boston, MA, 65 semester hours

9/1977-1/1979 Master of Science (Food Science), **Cornell University**, Ithaca, NY, approximately 48 semester hours

9/1973-6/1977 Bachelor of Science (Life Science: Applied Biology), **Massachusetts Institute of Technology**, Cambridge, MA, approximately 160 semester hours

## **PUBLICATIONS AND PRESENTATIONS**

### **ORIGINAL TECHNICAL REPORTS**

BRIGHT RA, Bright-Ponte, SJ, Palmer LAM, Rankin SK, Blok SV. Use of diagnosis codes to find blood transfusion adverse events in electronic health records. *JPS* 2022 Feb 21. DOI: 10.1097/PTS.0000000000000946.

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BRIGHT RA, Dowdy K, Rankin SK, Blok S, Palmer LA, Bright-Ponte SJ. New and Increasing Rates of Adverse Events Can be Found in Unstructured Text in Electronic Health Records using the Shakespeare Method. *medRxiv* 2021.01.12.21249674. DOI: 10.1101/2021.01.12.21249674.

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Transfusion Adverse Events Can be Found in Unstructured Text in Electronic Health Records using the ‘Shakespeare Method’. *medRxiv* 2021.01.05.21249239. DOI: 10.1101/2021.01.05.21249239.

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Mallory EK, de Rochemonteix M, Ratner A, Acharya A, Re C, BRIGHT R, Altman R. Extracting chemical reactions from text using Snorkel. *BMC Bioinformatics*. 2020 May 27;21(1):217. DOI: 10.1186/s12859-020-03542-1.

Mallory EK, Acharya A, Rensi SE, Turnbaugh P, BRIGHT RA, Altman RB. Chemical reaction vector embeddings: Towards predicting drug metabolism in the human gut microbiome. *Proc Pacific Symposium on Biocomputing 2018*. 2018. [https://doi.org/10.1142/9789813235533\\_0006](https://doi.org/10.1142/9789813235533_0006).  
Kass-Hout TA, Xu Z, Mohebbi M, Nelsen H, Baker A, Levine J, Johanson E, BRIGHT RA. OpenFDA: an innovative platform providing access to a wealth of FDA’s publicly available data. *JAMIA* 2015 Dec 7. Pii: 0cv153. DOI: 10.1093/jamia/ocv153.

Duggirala HC, Topping JM, Smith E, BRIGHT RA, Baker JD, Ball R, Bell C, Bouri K, Bright-Ponte SJ, Botsis T, Boyer M, Burkhart K, Condrey GS, Chen JJ, Chirtel S, Filice RW, Francis H, Jiang H, Levine J, Martin D, Oladipo T, O’Neill R, Palmer LAM, Paredes A, Rochester G, Sholtes D, Wong H-L, Xu Z, Szarfman A, Kass-Hout T. Use of data mining at the FDA. *JAMIA* 2015 Jul 23. Pii:ocv063. DOI: 10.1093/jamia/ocv063.

Zhan C, Kaczmarek R, Loyo-Berrios N, BRIGHT RA. Incidence and short-term outcomes of primary and revision hip replacement procedures in the United States: a 2003 nationwide claims-based analysis. *J Bone Joint Surg Am* 2007; 89(3):526-533.

Brown SL, BRIGHT RA, Dwyer DE, Foxman B. Breast pump adverse events: reports to the Food and Drug Administration. *J Hum Lact* 2005; 21(2):169-174.

Samore MH, Evans RS, Lassen A, Gould P, Lloyd J, Gardner RM, Abouzelof R, Taylor, C, Woodbury DA, Willy M, BRIGHT RA. Surveillance of medical device-related hazards and adverse events in hospitalized patients. *JAMA* 2004; 291:325-34.

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Moore RM, BRIGHT RA, Jeng LL, Sharkness CM, Hamburger SE, Hamilton P. The prevalence of internal orthopedic fixation devices in children in the United States, 1988. *Am J Public Health* 1993; 83:1028-1030.

BRIGHT RA, Moore RM, Jeng LL, Sharkness CM, Hamburger SE, Hamilton PM. The prevalence of tympanostomy tubes in children in the United States, 1988. *AJPH* 1993; 83:1026-1028.

BRIGHT RA, Jeng LL, Moore RM. National survey of self-reported breast implants: 1988 estimates. *J Long Term Effects of Med Implants*. 1993; 3(1):81-89.

Kaczmarek RG, Moore RM, BRIGHT RA. The relationship of maternal race and insurance status to prenatal ultrasound use in a national population. *Md Med J* 1992; 41(2):139-143.

BRIGHT RA, Everitt DE. Beta-blockers and depression: evidence against an association. *JAMA* 1992; 267:1783-1787.

Sharkness CM, Hamburger S, Kaczmarek R, Hamilton PM, BRIGHT RA, Moore RM Jr. Racial differences in the prevalence of intraocular lens implants in the United States. *Am J Ophthalmol* 1992; 114:667-674.

Jeng LL, Moore RM, Kaczmarek RG, Placek PJ, BRIGHT RA. How frequently are home pregnancy tests used? Results from the 1988 National Maternal and Infant Health Survey. *Birth* 1991; 18(1):11-13.

BRIGHT RA, Morrison AS, Brisson J, Burstein NA, Sadowsky NS, Kopans DB, Meyer JE. Histologic and mammographic specificity of risk factors for benign breast disease. *Cancer* 1989; 64:653-657.

BRIGHT RA, Morrison AS, Brisson J, Burstein NA, Sadowsky NS, Kopans DB, Meyer JE. Relationship between mammographic and histologic features of breast tissue in women with benign biopsies. *Cancer* 1988; 61:266-271.



BRIGHT RA, Potter NN. Acceptability and properties of carbonated apple juice. *Food Prod Dev* 1979; 13(4):34-37.

## **PATENT**

Hsieh D S-T, BRIGHT RA, Rha C. Method of making soybean beverages. US Patent 4,119,733; October 10, 1978. Canada Patent 1,083,879; 1980.

## **SOFTWARE**

BRIGHT RA. Definitions of terms in MIMIC III notes:

- <https://github.com/MIT-LCP/Shakespeare-Method>
- [https://github.com/MIT-LCP/Shakespeare-Method/blob/main/Definitions\\_of\\_some\\_terms\\_in\\_MIMIC\\_text\\_notes\\_Bright\\_20210913.csv](https://github.com/MIT-LCP/Shakespeare-Method/blob/main/Definitions_of_some_terms_in_MIMIC_text_notes_Bright_20210913.csv)
- [https://github.com/MIT-LCP/Shakespeare-Method/blob/main/Definitions\\_of\\_some\\_terms\\_in\\_MIMIC\\_text\\_notes\\_Bright\\_20210913.xlsx](https://github.com/MIT-LCP/Shakespeare-Method/blob/main/Definitions_of_some_terms_in_MIMIC_text_notes_Bright_20210913.xlsx)

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Appendix E -- Capability analysis of surveillance programs internal and external to CDRH with respect to surveillance goals. IN: Ensuring the safety of marketed medical devices: CDRH's medical device postmarket safety framework. January 18, 2006. Was available at <http://www.fda.gov/cdrh/postmarket/mdpi-report.pdf>.

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BRIGHT RA. The CDRH epidemiologist: a rare breed. *On Center* 1992, November: 4-5.

BRIGHT RA, Avorn J, Everitt DE. Medicaid data as a resource for epidemiologic studies: strengths and limitations. *J Clin Epidemiol* 1989; 42: 937-945.

## **PRESENTATIONS AT SCIENTIFIC MEETINGS**

BRIGHT RA. Topic Analysis is Like a Box of Chocolates: You Never Know What You Are Going to Get (talk). IN: Topics Drinking from the Data Firehose Session. 8th Annual Scientific Computing Days (SCD). FDA. Sep 29, 2020.

BRIGHT RA, Rankin S. Bloat-Ectomy: A Method for the Identification and Removal of Duplicate Text in the Bloated Notes of Electronic Health Records and Other Documents (poster). 2019 Scientific Computing Days Symposium. FDA. September 9-10, 2019.

BRIGHT R, Bright-Ponte S, Palmer LA, Blok S, Crane E. Demonstration of ngram frequency and cluster method for identifying signals of transfusion reactions (TR). International Society for Pharmacoeconomics and Outcomes Research, Baltimore, MD, May 21, 2018.

Phipps J, Mikhalchuk A, Johanson E, BRIGHT R, Bandler R, Griffin A, Hall L, Houle L. Healthy Citizen @ FDA: working to enhance public health through citizen-centric communication (accepted poster). FDA Science Forum, June 1, 2017.

Mallory E, Acharya A, BRIGHT R, Altman R. Synthesizing scientific knowledge to uncover the connection between drugs and the human gut microbiome (accepted poster). FDA Science Forum, May 31, 2017.

BRIGHT RA. IT and informatics innovation at FDA (invited talk). Fourteenth Annual Bio-IT World Conference and Expo '15, Boston, MA, April 23, 2015.

BRIGHT RA. Office of Informatics and Technology Innovation: A New Office in FDA (invited talk). Federal Health Community, Healthcare Information and Management Systems Society, USA, May 22, 2014.

BRIGHT RA. Approaching ideal surveillance (invited talk). 24<sup>th</sup> International Conference of the International Society for Quality in Health Care, Boston, MA, October 3, 2007.

BRIGHT RA. Pharmacoepidemiologic studies of devices and post-marketing surveillance, or, "How frequent are adverse medical device events?", 3er Encuentro Internacional de Farmacovigilancia (Third Pharmacovigilance International Meeting), Bogota, Colombia, September

26, 2006.

BRIGHT RA. Quantifying the threat to public health posed by adverse medical device events (invited talk). World Congress of Epidemiology, Seattle, WA, June 23, 2006.

BRIGHT RA. Introduction to session, "Frequency of adverse medical device events: impact on patient safety and role of HIT" (host talk). AHRQ's Annual Patient Safety and Health Information Technology Conference, Washington, DC, June 5, 2006.

BRIGHT RA. Literature on the frequency of adverse medical device events in hospital settings (submitted talk). AHRQ's Annual Patient Safety and Health Information Technology Conference, Washington, DC, June 5, 2006.

BRIGHT RA, Shen J. Using HCUPNet to estimate the frequency of adverse medical device events (submitted talk). AHRQ's Annual Patient Safety and Health Information Technology Conference, Washington, DC, June 5, 2006.

BRIGHT RA. Frontiers in surveillance of medical devices (invited talk). FDA Science Forum, Washington, DC. April 19, 2006.

BRIGHT RA, Shen JC. Use of a free, publicly-accessible data source to estimate hospitalizations related to adverse medical device events (poster). FDA Science Forum, Washington, DC. April 18-20, 2006. World Congress of Epidemiology, Seattle, WA, June 23, 2006.

Alderson N, Babu US, Chu P, Crone T, Elkins C, Fahmy RM, Gobburu JV, Johannessen J, Kavanaugh C, Kumar S, Major M, Manjanatha M, BRIGHT RA, Trinh H, Torosian SD, Uppoor RS, Woods T. Committee for the Advancement of FDA Science (CAFDAS): The FDA scientist's liaison to the Commissioner's Office (poster). FDA Science Forum, Washington, DC. April 18-20, 2006.

BRIGHT RA, Mermel L, Richards C, Yoder D. Mechanical and allergic adverse events related to central vascular catheters: epidemiology in the Medicare hospitalized surgical population, 2002 (poster). International Conference on Pharmacoepidemiology, Bordeaux, France, August 2004.

BRIGHT RA. Panel discussion before the Committee on Postmarket Surveillance of Pediatric Medical Devices, Institute of Medicine, Washington DC, June 24, 2004.

BRIGHT RA, Anderson S, Frost T, Wiessner P, Orme J, Clemmer T, Evans RS, Williamson J, Samore MH. Medical device problems in intensive care units: recognizing, recording, and resolving. Second Annual Conference for MedSun Representatives, Annapolis, MD, October 8, 2003.

Hefflin BJ and BRIGHT RA. Injuries Associated with Medical Devices: Pilot Study and Surveillance (Invited talk). All Injury NEISS Program Fall Meeting, Bethesda, MD, September 25, 2003.

BRIGHT RA, Dwyer DE. Retained menstrual tampons: hazards and epidemiology (Submitted abstract). International Society for Technology Assessment in Health Care 19<sup>th</sup> Annual Meeting, Canmore, Canada, June 23, 2003. International Conference on Pharmacoepidemiology, Philadelphia, PA, August 24, 2003.

Hefflin BJ, BRIGHT RA. NEISS medical device case collection (invited talk). NEISS Hospital Coordinator Meeting, Bethesda, MD, July 31, 2003.

BRIGHT RA, Kaye R, Samore MH. Patient safety research: a discussion of terminology, proposed definitions, and a conceptual model for adverse events involving medical devices (Submitted abstract). International Society for Pharmacoeconomics and Outcomes Research, Arlington, VA, May 20, 2003. International Society for Technology Assessment in Health Care 19<sup>th</sup> Annual Meeting, Canmore, Canada, June 24, 2003.

BRIGHT R, Anderson S, Frost T, Wiessner P, Orme J, Clemmer T, Evans RS, Samore MH. Directly-observed frequency of medical device-related problems in intensive care units (Submitted abstract). International Society for Technology Assessment in Health Care 19<sup>th</sup> Annual Meeting, Canmore, Canada, June 23, 2003.

Samore MH, Anderson S, Frost T, Wiessner P, Orme J, Clemmer T, Evans RS, BRIGHT RA. Direct observation in intensive care units: medical device-related problems associated with alarms (Submitted abstract). International Society for Pharmacoeconomics and Outcomes Research, Arlington, VA, May 19, 2003.

BRIGHT RA, Anderson S, Frost T, Wiessner P, Orme J, Clemmer T, Evans RS, Samore MH. Medical device problems in intensive care units: detection, dangers, and diversity of types (Submitted abstract). Society for Healthcare Epidemiology of America Final Program, Arlington, VA, April 7, 2003. International Society for Pharmacoeconomics and Outcomes Research, Arlington, VA, May 19, 2003. International Conference on Pharmacoepidemiology, Philadelphia, PA, August 22, 2003.

BRIGHT R. Sentinel Adverse Event Reporting Systems: An Update from CDRH (invited talk). Drug Information Association, Washington, DC, January 15, 2003.

BRIGHT R. The “How do we know what's *really* going on with medical device related problems in hospitals?” Game!!! (invited talk). First Annual MedSun Conference, Annapolis, MD, October 24-25, 2002.

BRIGHT R. Update on Medical Device Epidemiology and Surveillance (submitted symposium).

17<sup>th</sup> International Conference on Pharmacoepidemiology, Toronto, Canada, August 23-26, 2001.

BRIGHT R, Kessler LG. FDA's initiatives to improve adverse medical device event surveillance (submitted talk). 17<sup>th</sup> International Conference on Pharmacoepidemiology, Toronto, Canada, August 23-26, 2001.

Patterson K, BRIGHT RA, Barr H, Kaczmarek R. Quality and access: The Mammography Quality Standards Act (submitted talk). 17<sup>th</sup> International Conference on Pharmacoepidemiology, Toronto, Canada, August 23-26, 2001.

Gardner SN, Flack M. The Medical product Surveillance Network (MedSuN) Program (delivered submitted talk). 17<sup>th</sup> International Conference on Pharmacoepidemiology, Toronto, Canada, August 23-26, 2001.

BRIGHT RA, Marinac-Dabic D, Torrence M, Shahrokh S, Lilienfeld D, Schone E. Chorionic villus sampling and amniocentesis histories among births to military health care beneficiaries (Submitted talk). American Public Health Association 126<sup>th</sup> Annual Meeting and Exposition, Washington, DC, November, 1998.

Barton MB, Moore S, BRIGHT RA. Does managed care equalize access for poor elderly? Socioeconomic status and mammography utilization in a Medicare HMO (Submitted poster). 14<sup>th</sup> International Conference on Pharmacoepidemiology, Berlin, Germany, 16-19 August, 1998.

BRIGHT RA. Using epidemiology to study medical devices in women. (Invited talk), 20 min., Conference on Medical Device Epidemiology in Women, Rockville, MD, May 4-5, 1998.

BRIGHT RA, Donahue JG, Lacke L, Platt R. Using automated patient records for medical device epidemiology: preliminary explorations (Submitted poster). 13<sup>th</sup> International Conference on Pharmacoepidemiology, Lake Buena Vista, FL, August 24-27, 1997, and 1997 FDA Forum on Regulatory Sciences, Bethesda, MD, December 8-9, 1997.

BRIGHT RA, Silverman BG, Daley R, Ruhl CE, Brahin M, Morin R. A new menu-driven system for converting claims files into analysis datasets organized by case (Submitted poster). 13<sup>th</sup> International Conference on Pharmacoepidemiology, Lake Buena Vista, FL, August 24-27, 1997, and 1997 FDA Forum on Regulatory Sciences, Bethesda, MD, December 8-9, 1997.

BRIGHT RA, Graham D, Wise RP, Nelson RC, Szarfman A, Lu S. Automated safety signal detection at FDA's Center for Drug Evaluation & Research (Submitted oral presentation). 13<sup>th</sup> International Conference on Pharmacoepidemiology, Lake Buena Vista, FL, August 24-27, 1997.



BRIGHT RA. Methodologic issues in measuring extent of current use of medical devices (Submitted oral presentation). 13<sup>th</sup> International Conference on Pharmacoepidemiology, Lake Buena Vista, FL, August 24-27, 1997.

BRIGHT RA, Torrence ME, Gross TP. A preliminary study of apheretic device and ACE inhibitor interaction causing anaphylactoid reactions in dialysis patients (Submitted poster). Society for Epidemiologic Research, Snowbird, UT, June 21-24, 1995 and International Society for Pharmacoepidemiology, Montreal, Canada, August 27-30, 1995.

BRIGHT RA, Farup CE, Marinac-Dabic D, Kaczmarek RG, Moore RM. National patterns of reported maternal serum alpha-fetoprotein test use (Submitted poster). Society for Epidemiologic Research, June 16, 1993, Keystone, CO.

BRIGHT RA, Kaczmarek RG, Moore RM, Marinac-Dabic, D. National patterns of amniocentesis use: Results from the National Maternal and Infant Health Survey (Submitted poster). American Public Health Association 120th Annual Meeting and Exhibition, November 9, 1992, Washington, DC.

BRIGHT RA, Jeng LL, Sharkness CM, Hamilton PM, Hamburger SE, Moore RM. Use of tympanostomy tubes in children in the United States, 1988 (Submitted poster). FDA Science Expo '92, Rockville, MD, May 21-22, 1992.

BRIGHT RA, Moore RM, Jeng LL, Sharkness CM, Hamilton PM, Hamburger S. Use of fixation devices among children in the United States, 1988 (Submitted talk). FDA Science Expo '92, Rockville, MD, May 21-22, 1992.

BRIGHT RA, Moore RM, Jeng LL, Sharkness CM, Hamilton PM, Hamburger S. Use of fixation devices among children in the United States, 1988 (Submitted talk). Epidemiology Section, American Public Health Association Meeting, Atlanta, GA, November 13, 1991.

BRIGHT RA, Moore RM, Kaczmarek RG. The relationship of maternal race and insurance status to prenatal ultrasound use in a national population (Invited talk). Session sponsored by Radiological Health and Maternal and Child Health Sections at the American Public Health Association Meeting, Atlanta, GA, November 12, 1991.

BRIGHT RA, Sharkness CM, Moore RM, Kaczmarek RG, Jeng LL. Experience with home apnea monitors, United States, 1988 (Submitted poster). National Perinatal Association 1991 Annual Clinical Conference and Exposition, Boston, MA, November 7 - 9, 1991.

BRIGHT RA, Kaczmarek RG, Moore RM. Patterns of ultrasound use in a national population, U.S., 1988. National Perinatal Association 1991 Annual Clinical Conference and Exposition, Boston, MA, November 7 - 9, 1991.

BRIGHT RA, Jeng LL, Sharkness CM, Hamilton PM, Hamburger SE, Moore RM. Use of tympanostomy tubes in children in the United States, 1988 (Submitted poster). Society for Pediatric Epidemiologic Research, Buffalo, NY, June 11, 1991.

BRIGHT R, Sharkness C, Kaczmarek R, Hamburger S, Moore R. Artificial hips in the United States, 1988 (Submitted poster). Third National Injury Control Conference, Denver, CO, April, 1991.

BRIGHT R, Moore R, Jeng L, Sharkness C, Hamilton P, Hamburger S. Use of fixation devices among children in the U.S., 1988 (Submitted poster). Third National Injury Control Conference, Denver, CO, April, 1991.

BRIGHT R, Kaczmarek R, Sharkness C, Hamburger S, Hamilton P, Davis Y. Knee replacements due to injury: results of a national survey (Submitted poster). Third National Injury Control Conference, Denver, CO, April, 1991.

BRIGHT RA, Chown MJ, Everitt DE, Gurwitz J, Avorn J. Methodologic considerations in linking multiple databases for the study of AIDS epidemiology (Invited talk). American Statistics Association, Washington, DC, August, 1988.

BRIGHT RA, Avorn J, Everitt DE. (Submitted talk) International Conference on Pharmacoepidemiology, Minneapolis, MN, September 1987.

BRIGHT RA. Histologic and mammographic specificity of risk factors for benign breast disease (Submitted talk). Society for Epidemiologic Research, Amherst, MA, June 1987.

BRIGHT R, Morrison A, Brisson J, Burstein N. Relationships between mammographic image and histology in women who have benign biopsy (Submitted talk). Society for Epidemiologic Research, Chapel Hill, NC, June 1985.

## **OTHER PRESENTATIONS, EXTERNAL TO FDA**

“Earlier detection of new and increasing potential patient harms using the clinical notes in electronic healthcare records: The new Shakespeare Method” (invited 60 min talk). Presented to Health IT Research and Development Interagency Working Group meeting, online, February 24, 2021. Presented to Agency for Research and Healthcare Quality patient safety group, online, March 24, 2021.

“The FDA perspective on health informatics” (invited 50 min talk). Presented to 2018 Joint Class Day, Dietetic Internship, Department of Nutrition & Food Science, College of Agriculture and Natural Resources, University of Maryland, Baltimore, MD, January 29, 2018.

“Shakespeare Project” (5 min). Presented at HHS Data Science CoLaboratory Demonstration Day, Washington, DC, January 18, 2018.

“Shakespeare Electronic Health Records Project: Earlier detection of patient harms using big data techniques on electronic health record free text notes” (4 min invited talk with Drs. Lee Anne Palmer and Susan J Bright-Ponte). Presented at HHS Innovation Day, Washington, DC, July 14, 2016.

“Big Data Tools to Find Patient Harm in Health Records” (10 min invited talk with Drs. Lee Anne Palmer and Susan J Bright-Ponte). Presented to HHS IDEA Lab Ignite Program judges, virtually, February 12, 2016.

“openFDA” (30 min invited talk). Presented to delegation of three officials from South Korea’s Ministry of Food and Drug Safety, Silver Spring, MD, May 18, 2015.

“Office of Informatics and Technology Innovation: A New Office in FDA” (50 min invited lecture). Presented to Master of Public Health students, “Introduction to Public Health Informatics” course, Emory University, Atlanta, GA, via web, August 22, 2014.

“FDA’s Vision of Health IT” (1 hour invited talk), 2014 GovConNet Procurement Conference, Gaithersburg, MD, May 16, 2014.

“MedWatch FDA/VA Medical Device Adverse Event Reporting” (10 min), Health and Human Services Domain IT Steering Committee, Department of Health and Human Services, Washington, DC, May 29, 2013.

“Benefit Risk of T-Scan” (10 minutes) for an FDA Advisory Panel meeting on the T-Scan 2000 ED, CDRH, FDA, Gaithersburg, MD, August 29, 2006.

“Special Issues in the Study and Regulation of Medical Devices” (2 hours) for a course, “Advanced Topics in Pharmacoepidemiology,” Harvard School of Public Health, Boston, MA, May 16, 2006.

“Patient safety and adverse event surveillance: the FDA perspective relative to medical devices” (15 minutes), Division of Clinical Epidemiology seminar, Salt Lake City Veterans Administration Medical Center, Salt Lake City, UT, June 21, 2005.

“Surveillance of medical device-related hazards and adverse events in hospitalized patients” (1 hour), Agency for Healthcare Research and Quality, Rockville, MD, June 10, 2004.

“Epidemiology of Medical Devices” (1 hour), Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital, Boston, MA, May 18, 2004.

“Special Issues in the Study and Regulation of Medical Devices” (2 hours) for a course, “Advanced

Topics in Pharmacoepidemiology,” Harvard School of Public Health, Boston, MA, May 18, 2004.

“Injuries Associated with Medical Devices: Pilot Study and Surveillance” (1 hour) with Dr. Brock Hefflin for the All Injury NEISS Program Fall Meeting, Bethesda, MD, September 25, 2003.

“NEISS Medical Device Case Collection” (1 hour) with Dr. Brock Hefflin as training for NEISS coordinators, Consumer Product Safety Commission, Bethesda, MD, July 2003.

“The FDA View of Vaginal Douches Epidemiology,” presented to the FDA Advisory Panel, 15 minutes, Gaithersburg, MD, April 1997, and the Over The Counter Scientific Rounds, Center for Drug Evaluation and Research, FDA, Rockville, MD, May 1997.

At the FDA Workshop on Methods to Estimate Medical Device Denominator Data, made a 10 minute introductory speech on the agenda and administrative information, and moderated two 1 and a half hour sessions of prepared talks and informal discussions, Rockville, MD, September 1996.

Seminar "The Epidemiology Program at the FDA: Medical devices and radiation-emitting electronic products," to Preventive Medicine Residents, 1 hour, Johns Hopkins University, Baltimore, MD, November 1995.

Presentation "Postmarket Surveillance of Medical Devices -- The Current Situation at FDA," at the 1994 Eye Care Technology Forum, 15 min., Bethesda, MD, December 1994.

Presentation to Health Industry Manufacturers Association and National Electrical Manufacturers Association on trend analysis of adverse event reports, 5 min., Rockville, MD, June 1994.

Presentation on guidelines for epidemiologic studies of penile inflatable implants and testicular implants to FDA Advisory Panel, 5 min., Rockville, MD, April 1993.

Presentation of Epidemiology Branch research using the National Maternal and Infant Health Survey, to the National Center for Health Statistics and FDA Interagency Advisory Group, 15 min., Rockville, MD, June 1992.

Personal testimony at the Public Hearing on the Recruitment, Retention, Re-entry, and Advancement of Women in Biomedical Careers, sponsored by the Office of Women's Health and Research, National Institutes of Health, Bethesda, MD, 10 min., March 1992.

Presentation of silicone breast implant prevalence to FDA Advisory Panel, Bethesda, MD, 5 min., February 1992.

Presentation of the hazards associated with protective restraints, made to the manufacturers in a meeting sponsored by Health Industry Manufacturers Association, Washington, DC, 15 min., October, 1991.

Presentation on breast implants, to the National Center for Health Statistics and FDA Interagency Advisory Group, 15 min., Rockville, MD, January 1991.

Presentation on latex hypersensitivity, to the National Center for Health Statistics and FDA Interagency Advisory Group, 15 min., Rockville, MD, January 1991.

Presentation to NIH Site Visitors on proposal to study breast cancer risk factors, Tufts University School of Medicine, Boston, MA, January 1989.

Lecture on the impact of computers on epidemiologic research capabilities, to class learning about computers and society, Boston College, Newton, MA, 45 min., Spring 1987 and Spring 1988.

Seminar on benign breast disease at University of Massachusetts, Amherst, MA, 45 min., May 1984.